REMARKS

Claims 70-77 are pending in this application.

Claims 1-69 have been cancelled without prejudice or disclaimer. Claims 70-77 have been newly added. Support for new claims 70-77 appears throughout the specification and claims as originally filed. No new matter has been added.

Claims 1-69 have been canceled without prejudice or disclaimer for the sole reason of advancing prosecution. Applicants, by canceling these claims, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein in a continuing application.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 4, 5, and 9-12, have been rejected under 35 USC § 112, second paragraph.

The Examiner asserts that the term "compound" and the term "derivative" are not clear.

Claims 4, 5, and 9-12 have been canceled without prejudice or disclaimer. Accordingly, this rejection is moot.

With regard to new claims 70-77, in view of the following this rejection is respectfully traversed.

New claims 70-77 do not recite the term "compound" or the term "derivative." More specifically, new claim 71 now recites the specific compounds that are encompassed by phenoxy-3-propylamine compounds or derivatives.

In view of the foregoing, it is submitted that claims 70-77, are clear and definite within the meaning of 35 USC § 112, second paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At page 4 of the Official Action, claims 1-3, 7, 8, 14, 15, and 63, have been rejected under 35 USC § 112, first paragraph as lacking enablement.

The Examiner asserts that the specification, while being enabling for a composition comprising certain specific antidepressant and antipsychotic agents such as those examples explicitly recited on pp. 15-16 of the instant specification, does not provide enablement for any cyclic psychotropic agent, any antidepressant or antipsychotic, or any serotonin and/or noradrenaline reuptake inhibitor.

Claims 1-3, 7, 8, 14, 15, and 63 have been canceled without prejudice or disclaimer. Accordingly, this rejection is moot.

With regard to new claims 70-77, in view of the following this rejection is respectfully traversed.

In order to make an enablement rejection, the Examiner has the initial burden to establish a *reasonable* basis to question the enablement provided for the claimed invention. *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993).

The test under 35 U.S.C. § 112, first paragraph, for determining compliance with the enablement requirement is whether one skilled in the art could make or use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988).

Applicant asserts that the specification enables the full scope of newly presented claim 70-77. Claims 70-77 are directed to monocyclic antidepressants only.

The enablement provision of the Patent Act requires that the patentee provide a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112, ¶ 1 (2000). The purpose of this requirement is to ensure that "the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999); *see also* Donald S. Chisum, 3 *Chisum on Patents* § 7.01 (2002).

Accordingly, the specification must provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). "The key word is 'undue,' not experimentation.'" *Wands*, 858 F.2d 731, 737 (Fed. Cir.

1988). Routine experimentation does not constitute undue experimentation. *See Johns Hopkins University v. Cellpro, Inc.,* 152 F.3d 1342 (Fed. Cir. 1998). That is, the specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation. *See, e.g., Nat'l Recovery Techs.*, 166 F.3d at 1196 ("The scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation."); *Wands*, 858 F.2d at 736-37 ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *See In re Wright,* 999 F.2d 1557 (Fed. Cir. 1993).

Although the ultimate determination of whether one skilled in the art could make and use the claimed invention without undue experimentation is a legal one, it is based on underlying findings of fact. *CFMT*, 349 F.3d at 1337. Furthermore, "[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Wands*, 858 F.2d at 737.

Some of these considerations, commonly referred to as "the *Wands* factors," include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art,

and (8) the breadth of the claims." *Id.; see also Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (stating that the *Wands* factors "are illustrative, not mandatory" and that what is relevant to an enablement determination depends upon the facts of the particular case).

In the present case, Applicant asserts that the specification, figures, and examples, provide ample guidance to the skilled artisan in view of the state of the art at the time the application was filed, to make and use the subject matter of claims 70-77 without undue experimentation.

Further, Applicants note that the court in *In re Wright* held that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.

The present specification at page 15, describes monocyclic antidepressants, as recited in claims 70-77. The specification describes non-exhaustive lists of examples of monocyclic antidepressants.

Reading the claims in view of the specification, a skilled artisan would be able to easily ascertain the scope of the presently claimed subject matter. Additionally, as monocyclic antidepressants including those disclosed are well known to the skilled artisan, there would be no need for undue experimentation. Accordingly, Applicants submit that, in view of the *In Re Wands* factors the present specification enables the skilled artisan to make and use the full scope of the presently claimed subject matter. Therefore, it is submitted that the claims are fully enabled by the specification.

In view of the foregoing, Applicants submit that the present specification enables the skilled artisan to make and use the full scope of the subject matter as claimed in new claims 70-77, within the meaning of 35 USC § 112, first paragraph. Thus, the Examiner is respectfully requested to withdraw this rejection.

III. At page 9 of the Official Action, claims 1-6, 14-15, and 63, have been rejected under 35 USC § 102(e), as being anticipated by Sawynok et al.

The Examiner asserts that Sawynok et al. (US Patent No. 6,211,171) discloses a composition comprising a specific tricyclic, second generation, or third generation antidepressant preferably formulated for local use as recited in instant claims 1-3 and 14-15. Additionally, the Examiner asserts that the antidepressant of Sawynok et al. is preferably one of the tricyclic antidepressants including clomipramine, imipramine, or amtriptyline. The Examiner further asserts that the antidepressant of Sawynok et al. could be a second or third generation antidepressant including trazodone, bupropion, or venlafaxane as recited by instant claims 4-6. Additionally, the Examiner asserts that the compositions of Sawynok et al. are inherently the same as the subject matter recited in present claims 61-69.

Claims 1-6, 14-15, and 63, have been canceled without prejudice or disclaimer. Accordingly, this rejection is moot.

With regard to new claims 70-77, in view of the following this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. R*ichardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

"For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art...The reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." *See In re Spada,* 911 F.2d 705 (Fed. Cir. 1990). Although the disclosure requirement presupposes the knowledge of one skilled in the art, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. *Id.*

"Summary judgment of inherency anticipation was improper because of a material fact issue whether a prior art reference's process necessarily produced the claimed invention's features." *See Continental Can Company USA, Inc. v. Monsanto Co.,* 948 F.2d 1264 (Fed. Cir. 1991). "Consistent with the law of inherent anticipation, an inherent property must necessarily be present in the invention described by the count, and it must be so recognized by persons of ordinary skill in the art." *Id.* "The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation." *See Electro*

Medical Systems, S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048 (Fed. Cir. 1994).

In *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995), the court held that the patent claim in suit was not inherently anticipated where the prior art process produced alternate forms. More specifically, the Glaxo court held that Form 2 of ranitidine was not "inherently and necessarily" produced in Example 32 of Glaxo's patent. The question is whether the missing element "is necessarily present in the thing described in the reference and that it would be so recognized." *See Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373 (Fed. Cir. 2002). Regarding recognition, the question is whether one skilled in the art would read the prior art reference as inherently disclosing the invention. *Id.*

"Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *See In re Oelrich,* 666 F.2d 578, 581 (CCPA 1981). "Occasional results are not inherent." *See Mehl/Biophile International Corp. v. Milgraum,* 192 F.3d 1362 (Fed. Cir. 1999). "A reference includes an inherent characteristic if that characteristic is the natural result flowing from the reference's explicitly explicated limitations." *See Continental Can Company USA, Inc., supra.*

At pages 10 and 11 of the final Official Action, the Examiner in response to applicants arguments, states the following;

> "Applicant argues that Sawynok et al. does not teach a composition for treating a benign hyperproliferative skin disorder...Applicant's claimed composition does not differ from that of Sawynok et al. in

> any manner that would indicate that the composition of Sawynok et al. is not suitable for the intended use of treating benign hyperproliferative skin disorders."

Applicants respectfully submit that the presently claimed formulation differs from the formulation of Sawynok et al. both in the active agent claimed and in the amount of the active agent claimed. Sawynok et al. describes an amount of a tricyclic antidepressant effective for treating inflammation or pain while the present claims recite an amount of at least one monocyclic antidepressant therapeutically effective for treating a hyperproliferative skin disorder.

New claim 70 is directed to a topical pharmaceutical composition, comprising a topically acceptable carrier and a therapeutically effective amount of at least one monocyclic antidepressant for treating a hyperproliferative skin disorder associated with excessive proliferation of skin cells. Claims 71-77 are directly or indirectly dependent on independent claim 70.

In contrast, Sawynok et al. is directed to analgesic formulations comprising ***tricyclic antidepressants*** for local administration in ***an amount effective for treating local inflammation and neuropathic pain***. The Examiner admits that Sawynok et al. discloses a different utility, i.e., the treatment of local inflammatory and neuropathic pain.

Sawynok et al. teaches neither the presently claimed monocyclic antidepressant nor the presently claimed amount of monocyclic antidepressant, i.e., that amount that is therapeutically effective for treating a hyperproliferative

skin disorder. Thus, Sawynok et al. does not expressly or inherently teach each and every element of present independent claim 70.

In view of the foregoing, it is submitted that Sawynok et al. does not teach, either expressly or inherently, each and every element of present claims 70-77, as required for anticipation under 35 USC § 102 (e). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. At page 11 of the Official Action, claims 1-4, 7-15, and 63, have been rejected under 35 USC § 102(b), as being anticipated by Beltner.

The Examiner asserts that Beltner (EP 0 168 626) anticipates claims 1-4, 7-15 and 61-69 because the compositions disclosed in Beltner are antipsychotic and antidepressant drugs that comprise the same ingredients as those of the claimed invention, and therefore inherently possess activity against proliferative dermatological diseases.

Claims 1-4, 7-15, and 63 have been canceled without prejudice or disclaimer. Accordingly, this rejection is moot.

With regard to new claims 70-77, in view of the following this rejection is respectfully traversed.

The test for anticipation is discussed in detail above with regard to the previous rejection.

New claim 70 is directed to a topical pharmaceutical composition, comprising a topically acceptable carrier and a therapeutically effective amount of at least one monocyclic antidepressant for treating a hyperproliferative skin

disorder associated with excessive proliferation of skin cells. Claims 71-77 are directly or indirectly dependent on independent claim 70.

Beltner is directed to a specific composition for the manufacture of a medicament for the therapeutic treatment of trauma to the skin that can include fluphenazine, chlorprothixene, or clozapine, or imipramine or amitriptyline, which are compounds that have the ability to interfere with the action of calcium clamodulin complex. Beltner describes that trauma to the skin can include burn, sunburn and frostbite.

Applicants respectfully submit that the presently claimed formulation differs from the formulation of Beltner both in the active agent claimed and in the amount of the active agent claimed. Beltner describes an amount of fluphenazine, chlorprothixene, or clozapine, or imipramine or amitriptyline, effective for treating trauma, while the present claims recite an amount of at least one monocyclic antidepressant therapeutically effective for treating a hyperproliferative skin disorder.

Beltner teaches neither the presently claimed monocyclic antidepressant nor the presently claimed amount of monocyclic antidepressant, i.e., that amount that is therapeutically effective for treating a hyperproliferative skin disorder. Thus, Beltner does not expressly or inherently teach each and every element of present independent claim 70.

In view of the foregoing, it is submitted that Beltner does not teach, either expressly or inherently, each and every element of present claims 70-77, as

required for anticipation under 35 USC § 102 (e). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. At page 14 of the Official Action, claims 1-10, 14-15, and 61-69 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 184-206 of co-pending Application No. 10/432,875.

The Examiner asserts that although the claims are not identical, they are not patentably distinct from each other because claims 184-206 of the '875 application anticipate the instant claims.

Claims 1-10, 14-15, and 61-69 have been canceled without prejudice or disclaimer. Accordingly, this rejection is moot.

With regard to new claims 70-77, in view of the following this rejection is respectfully traversed.

In an Amendment and Response filed on May 31, 2007 in the co-pending '875 application, claims 1-207 were canceled without prejudice or disclaimer and new claims 208-219 were added. New claims 208-219 are now limited to methods. More specifically, claims 208-219 of the '875 application are now limited to ***methods*** for treating specific proliferative skin disorders comprising topically administering to a subject in need thereof a therapeutically effective amount of at least one ***bicyclic antidepressant***.

In complete contrast thereto, present claims 70-77 are directed to a topical pharmaceutical compositions. More specifically, present claims 70-77 are directed to ***topical pharmaceutical compositions*** comprising a topically

acceptable carrier and a therapeutically effective amount of at least one ***monocyclic antidepressant*** for treating a hyperproliferative skin disorder associated with excessive proliferation of skin cells.

Accordingly, it is submitted that the pending claims of the '875 application do not anticipate present claims 70-77. Further, it is submitted that the present claims are patentably distinct from the pending claims of the '875 application.

In view of the foregoing, it is submitted that the present claims are patentably distinct from the claims pending in the co-pending '875 application. Thus, the Examiner is respectfully requested to withdraw this provisional rejection.

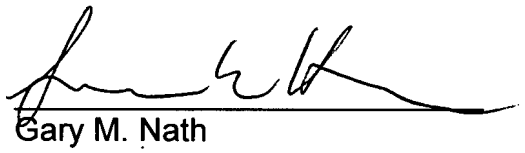
CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants hereby petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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